UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re Gabapentin Patent Litigation	MDL Docket No. 1384 Master Docket No. 00-CV-2931 (FSH) (PS)
This Document Relates To: Civil Action No. 00-CV-2931 Civil Action No. 00-CV-3522	Civil Action Nos. 00-CV-2931; 00-CV-3522; 00-CV-4168; 00-CV-4589; 00-CV-6073; 01-CV-0193; 01-CV-1537; 01-CV-2194 **Motion Return Date: October 6, 2008** ***DOCUMENT ELECTRONICALLY FILED***

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS OR STRIKE CERTAIN AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

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PRELIMINARY STATEMENT

Warner-Lambert contends that Purepac has not alleged a viable unclean-hands claim or defense because Warner-Lambert's misconduct—its illegal marketing of Neurontin for off-label uses—does not relate to the relief that Warner-Lambert requests. But Warner-Lambert's illegal marketing activities relate directly to its request for an injunction prohibiting Purepac from selling gabapentin products for all uses, including the off-label uses that Warner-Lambert targeted with its unlawful scheme.

Warner-Lambert also contends that Purepac has not alleged a viable patent-misuse claim or defense because Warner-Lambert did not broaden the physical or temporal scope of the '482 patent. But Warner-Lambert deliberately—for anticompetitive purposes—delayed the '482 patent's issuance and, therefore, its expiration. By intentionally postponing the term of the patent monopoly, Warner-Lambert broadened the '482 patent's temporal scope and engaged in patent misuse.

Warner-Lambert's motion to dismiss Purepac's antitrust and New Jersey common-law unfair-competition counterclaims is baseless and should be denied for several reasons. First, Warner-Lambert rehashes arguments that Judge Lifland already rejected when he denied Warner-Lambert's motion to dismiss Purepac's counterclaims in December 2000. Second, Warner-Lambert mischaracterizes Purepac's monopolization claim and applies the wrong antitrust analysis by inappropriately "compartmentalizing the various factual components [of that claim] and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). Third, Warner-Lambert raises disputed factual issues, including complex factual questions of causation, that should not be resolved upon a Rule 12(b)(6) motion. Fourth, Warner-Lambert incorrectly ignores several of the anticompetitive effects that Purepac alleges resulted from Warner-Lambert's monopolization scheme.

BACKGROUND

Neurontin (gabapentin anhydrous) has been "instrumental" to Warner-Lambert's growth. For instance, from 2000 through 2004, before generics entered the market, Neurontin generated annual revenue for Warner-Lambert as high as $2 billion. (Countercl. ¶¶ 80-81.) Warner-Lambert has sold Neurontin since early 1994, after the FDA approved it in December 1993 for use as "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." (*Id.* ¶¶ 75, 78.) At the time, however, the only patents protecting Warner-Lambert's gabapentin anhydrous monopoly from generic entry—Warner-Lambert's '175 and '544 patents—were due to expire in May 1994 and May 1995, respectively. (*Id*. ¶¶ 82, 84.) To forestall competition to its highly profitable product, Warner-Lambert engaged in a multi-faceted scheme to prevent generic entry by predatorily abusing the Hatch-Waxman Act and the rules and regulations of the Food and Drug Administration ("FDA") and the Patent and Trademark Office ("Patent Office"). (*Id.* ¶¶ 104-87.)

Warner-Lambert's Fraudulent Orange Book Submissions: One component of Warner-Lambert's monopolization scheme was its fraudulent listing of its '476 and '479 patents in the FDA's Orange Book. (Countercl. ¶¶ 123-47.) By doing so, Warner-Lambert unilaterally delayed Purepac's entry into the gabapentin anhydrous market. (*Id.* ¶¶ 123, 135, 148-57.)

From 1994 through 2000, Warner-Lambert knowingly submitted several false declarations to the FDA to list its '476 and '479 patents in the Orange Book and to maintain those listings. (*Id.* ¶¶ 123-140.) Warner-Lambert's declarations were false and improper because they purposely ignored FDA's rules and regulations that forbade Warner-Lambert from listing the patents in the Orange Book unless the patents "claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product" and, for method-of-use patents, "**only** on those patents that claim indications or other

conditions of use of a pending or approved application" (21 C.F.R § 314.53(b) (1994) (emphasis added)).[1] (Countercl. ¶¶ 63-64, 125-33, 136-39, 153-54.) Warner-Lambert knew that its '476 and '479 patents did not meet these FDA requirements for Orange Book listing but Warner-Lambert submitted declarations to the FDA that certified that they did meet these FDA requirements. (*Id.*) Warner-Lambert's internal analyses confirm that it knew its Orange Book listings were improper. (*Id.* ¶¶ 141-47.)

The '476 patent covers gabapentin monohydrate, which is **not** the FDA-approved gabapentin anhydrous sold as Neurontin. (*Id.* ¶¶ 87, 127-28.) Warner-Lambert knew that gabapentin monohydrate was not the drug in Neurontin or a component of Neurontin. (*Id.* ¶¶ 129-32.) But Warner-Lambert twice falsely declared that the '476 patent "covered a crystal form and the use of Neurontin" and later also that it "covered the formulation, composition, and/or method of use of Neurontin." (*Id.* ¶ 91, 125-26.) Without these false statements, Warner-Lambert could not have listed the '476 patent in the Orange Book. (*Id.* ¶¶ 66, 124.)

The '479 patent covers the use of gabapentin anhydrous for treating neurodegenerative diseases, e.g., Parkinson's and Lou Gehrig's disease. (Countercl. ¶ 88.) Warner-Lambert never sought FDA approval for the treatment of neurodegenerative diseases. (*Id.*) Indeed, a full record will reveal that Warner-Lambert's own research has found that gabapentin anhydrous has no meaningful utility in the treatment of neurodegenerative diseases. (Defenses ¶ 22.) Warner-Lambert nevertheless declared to the FDA that the '479 patent claimed an approved method of

[1] These regulations became effective in October 1994, but it had been the FDA's published policy since 1989 that NDA applicants should "submit information **only** on those patents that claim an **approved drug product or approved method of using such drug product**, or drug product or a method of using such drug product for which the applicant has submitted an application to obtain FDA approval." Proposed Rule, Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28908-09 (July 10, 1989) (emphasis added). The 1989 policy expressly replaced prior policies to the contrary. *See id.* at 28874.

using Neurontin. (Countercl. ¶¶ 136-40, 153-54.) Without these false statements, Warner-Lambert could not have listed the '479 patent in the Orange Book. (*Id.* ¶¶ 66, 124, 139-40.)

Warner-Lambert's false Orange Book submissions were part of a larger scheme to delay generic entry. With its January 1992 NDA—and in a September 1993 amendment thereto—Warner-Lambert did not list the '476 or '479 patents in the Orange Book. (*Id*. ¶¶ 89, 116.) But with the expiration of the '175 and '544 patents looming, Warner-Lambert subsequently improperly added the '476 and '479 patents to the Orange Book to provide new protection against generic entry. (*Id.* ¶¶ 90, 117-18, 123.) Tellingly, Warner-Lambert listed the '476 and '479 patents in the Orange Book only after the FDA approved its NDA in December 1993, even though those patents were issued in 1990 and 1992, respectively. (*Id.* ¶¶ 75, 87-88, 90.)

Warner-Lambert's fraudulent Orange Book listings of the '476 and '479 patents imposed significant regulatory impediments to Purepac's entry, including a 30-month stay of FDA approval of generic gabapentin. (Countercl. ¶¶ 135, 148-57.) But Warner-Lambert's fraudulent Orange Book submissions had a second purpose: to facilitate Warner-Lambert's abuse of Patent Office process to obtain a second 30-month stay of FDA approval of generic gabapentin.

Warner-Lambert's Abuse of Patent Office Process: Since 1990, Warner-Lambert had been prosecuting another patent that it intended to use as protection against generic gabapentin entry, which would ultimately become the '482 patent. (*Id*. ¶ 105.) Warner-Lambert abused the Patent Office's rules and regulations to delay the issuance of that patent until April 2000, including by repeatedly advancing the same arguments in response to Patent Office inquiries, by withholding prior art, by unnecessarily withdrawing its allowed application, and by filing unnecessary continuation application(s). (*Id.* ¶¶ 105-15.) Warner-Lambert used these tactics to cause the '482 patent to issue at a time that would require the FDA to stay approval of Purepac's generic gabapentin by a second 30-month period—on top of the 30-month stay afforded by the

fraudulent listing of the '476 patent. (*Id.* ¶¶ 119-22.) Warner-Lambert's misconduct before the Patent Office was part of its larger effort to abuse the FDA's Hatch-Waxman rules and regulations. (*Id.* ¶¶ 104, 115.) Warner-Lambert triggered the second 30-month stay when it commenced this action in June 2000 alleging infringement of the '482 patent.

But for Warner-Lambert's misconduct before the Patent Office, the '482 patent would have issued in March 1995 (or earlier), instead of April 2000. (*Id.* ¶¶ 114, 118, 121.) In January 1995, Warner-Lambert avoided the '482 patent's scheduled March 1995 issuance by withdrawing the allowed application and filing a last-minute continuation application, suddenly disclosing prior art it could and should have disclosed much earlier. (*Id.* ¶¶ 106-13.) Warner-Lambert could risk delaying the '482 patent's issuance because it had recently improperly listed the '476 patent in the Orange Book to provide a basis for a first 30-month stay. (*Id.* ¶¶ 116-19, 123.) But for the listing of the '476 patent, Warner-Lambert would have needed the '482 patent to issue in March 1995, because the '544 patent was due to expire in May 1995. (*Id.* ¶¶ 116-20.)

Absent Warner-Lambert's misconduct before the Patent Office—which delayed the '482 patent's issuance—Warner-Lambert would have sued on the '482 patent in June 1998, shortly after Purepac filed its first ANDA, instead of June 2000. (*Id.* ¶¶ 120-21.)

Warner-Lambert's Sham Lawsuits: Yet another integral component of Warner-Lambert's monopolization scheme was a series of sham lawsuits against Purepac and Apotex Corp., another generic drug manufacturer seeking to market generic gabapentin. (Countercl. ¶¶ 152, 158-80.) Warner-Lambert used these sham suits to trigger the 30-month stay made possible by its false Orange Book listings of the '476 patent and to impose cost on Purepac.

In March 1998, Purepac filed an ANDA seeking FDA approval to market generic gabapentin anhydrous capsules after the '544 patent expired (which at that point had been extended to January 2000). (*Id.* ¶¶ 94, 96.) As a direct result of the improper Orange Book

listing of the '476 patent, Purepac had to (and did) (a) submit with its ANDA a certification that that patent was invalid or would not be infringed by Purepac's generic gabapentin anhydrous capsules ("Paragraph IV Certification") and (b) notify Warner-Lambert of its intention to seek ANDA approval before the '476 patent expired. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) & (B)(i) (1998); (Countercl. ¶ 97). Warner-Lambert sued Purepac for patent infringement within 45 days of that notice (the "Capsule Action"), which automatically barred ANDA approval for 30 months or until a court decision issued. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (1998); (Countercl. ¶ 163). Warner-Lambert asserted infringement of both the '476 and '479 patents. (Countercl. ¶ 164.)

Warner-Lambert filed and pursued the Capsule Action without an objective basis, solely to foreclose Purepac from market entry by imposing regulatory hurdles and extra cost. (*Id.* ¶¶ 158, 162, 170.) Purepac will prove that Warner-Lambert did not perform any pre-complaint investigation because it already knew that its infringement theories regarding the '476 and '479 patents were defective. (*Id.* ¶¶ 129-30, 141-47, 159, 160-62, 165; Defenses ¶ 22.) Purepac will prove that Warner-Lambert purposely delayed discovery and continued the Capsule Action after receiving conclusive evidence of noninfringement of the '476 patent. (Countercl. ¶¶ 171-74.)

After Purepac filed its ANDA to market generic gabapentin anhydrous in tablet form in September 1999, Warner-Lambert sued Purepac again asserting near identical claims of infringement of its '476 and '479 patents (the "Tablet Action"), even though it had already received conclusive evidence of noninfringement in the Capsule Action. (*Id.* ¶¶ 95, 164-68, 170-77.) Warner-Lambert filed the Tablet Action for the sole purpose of imposing additional cost and regulatory hurdles on Purepac. (*Id.* ¶¶ 164, 168, 170, 175, 178.) Warner-Lambert pursued a similar baseless action against Apotex for its gabapentin anhydrous capsules. (*Id.* ¶ 152.)

Effects of Warner-Lambert's Monopolization Scheme: Warner-Lambert's carefully coordinated scheme to abuse the regulatory framework of the Hatch-Waxman Act imposed a

number of different impediments to Purepac's market entry. From June 1998 through May 2003, Warner-Lambert forced Purepac to divert its resources to defending two sham lawsuits and bearing the associated costs. (Countercl. ¶¶ 158, 164, 176-77.) Warner-Lambert delayed the '482 patent litigation for two years. (*Id.* ¶¶ 120-21.) And Warner-Lambert gained two 30-month stays, which foreclosed Purepac from the market until December 2002. (*Id.* ¶¶ 122-23, 135.)

Warner-Lambert's monopolization scheme also caused multiple disputes and lawsuits involving the FDA, Purepac, and Apotex, (a) about whether Purepac had to file a Paragraph IV Certification for the '479 patent, and (b) about whether only one 180-day exclusivity period applied to all of Warner-Lambert's Orange Book patents or whether 180-day exclusivity applied patent by patent.[2] (*Id.* ¶¶ 148-56.) Warner-Lambert had prompted and fueled these lawsuits by fraudulently listing the '476 and '479 patents in the Orange Book, by refusing to delist, and by alleging in its sham lawsuits that Purepac needed a Paragraph IV Certification with respect to the '479 patent. (Amundson Decl. Ex. 1 ¶ 19; Ex. 2 ¶ 19.)[3]

During the lawsuits with the FDA and Apotex that resulted from Warner-Lambert's monopolization scheme, FDA approval of Purepac's ANDAs remained contested. In fact, in the last of those lawsuits, the D.C. Circuit stayed ANDA approval from July through September 2004. (Amundson Decl. Ex. 3 (staying FDA approval of ANDA); Ex. 4 (vacating stay).) After the D.C. Circuit permanently lifted the stay, Purepac promptly launched generic products in October 2004. (Amundson Decl. Ex. 5 (denying emergency petition to reinstate stay of FDA

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[2] *See Purepac Pharm. Co. v. Thompson*, No. 02-1657 (D.D.C. filed Aug. 21, 2002); *TorPharm, Inc. v. Thompson*, No. 03-0254 (D.D.C. filed Feb. 14, 2003); *Apotex, Inc. v. FDA*, No 04-00605 (D.D.C. filed April 14, 2004); *Purepac Pharm. Co. v. Thompson*, No. 02-5410 (D.C. Cir. appeal docketed Dec. 12, 2002); *TorPharm, Inc. v. Thompson*, No. 03-5121 (D.C. Cir. appeal docketed Apr. 28, 2003); *Apotex, Inc. v. FDA*, No. 04-5211 (D.C. Cir. appeal docketed June 9, 2004).

[3] The citations to "Amundson Decl." and "Suppl. Amundson Decl." refer to Steven M. Amundson's declarations submitted in support of Purepac's opposition to Warner-Lambert's motion to dismiss or strike certain defenses and counterclaims.

approval).) Purepac did not launch earlier because that would have meant that Purepac not only had to risk liability for infringement of the '482 patent, but also the possibility that its approval would have been revoked after entering the market. Moreover, a court-ordered stay of ANDA approval, like the one the D.C. Circuit imposed in July 2004 in *Apotex v. FDA*, would have compromised Purepac's 180-day exclusivity had Purepac been on the market at that time.

But for Warner-Lambert's monopolization scheme, the '476 and '479 patents would not have been listed and litigated, the '482 patent litigation would have started in June 1998 (triggering only one 30-month stay ending in December 2001), and the FDA and Apotex lawsuits would not have occurred. Absent these improper acts, Purepac could have received FDA approval and launched its products much earlier than it did. (Countercl. ¶¶ 103, 157, 181.)

Warner-Lambert's Illegal Off-Label Promotional Activities: To avoid duplication and redundancy, Purepac incorporates by reference the factual background in the August 11, 2008 joint memorandum of the Teva and IVAX defendants. *AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc.*, No. 05-5333, 2008 WL 2668803, at *16 n.7 (D.N.J. July 1, 2008).

ARGUMENT

I. Purepac's Detailed Allegations Satisfy Rules 8(a) and 12(b)(6)

Rule 8(a) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). To satisfy this notice-pleading requirement, a claimant need only allege "enough factual matter (taken as true) to suggest the required elements" of the claim. *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). In ruling on a motion to dismiss under Rule 12(b)(6), a court must accept all factual allegations as true, construe the pleading in the light most favorable to the claimant, and determine whether, under any reasonable reading of the pleading, the claimant may obtain relief. *Id.* at 233 (citing *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1968-69 (2007)).

Warner-Lambert relies on Rule 12(f) in seeking to strike Purepac's unclean-hands and patent-misuse defenses as "insufficient." (Pls.' Br. 12.) Warner-Lambert relies on Rule 12(b)(6) in seeking to dismiss Purepac's unclean-hands and patent-misuse counterclaims. (Pls.' Br. 14-24.) Because the standard for a motion to dismiss under Rule 12(b)(6) governs the sufficiency of a defense under Rule 12(f), Purepac addresses Warner-Lambert's arguments together. *See, e.g.*, *Mars Inc. v. JCM Am. Corp*., No. 05-3165, 2006 WL 1704469, at *4 (D.N.J. June 14, 2006).

In the Third Circuit "antitrust complaints, in particular, should be liberally construed." *In re Hypodermic Prods. Antitrust Litig.*, MDL No. 1730, Master Docket No. 05-CV-1602, 2007 WL 1959224, at *5 (D.N.J. June 29, 2007) (citing *Pennsylvania v. Pepsico, Inc*., 836 F.2d 173, 179 (3d Cir. 1988)). Purepac's allegations contain more than "enough factual matter to suggest the required element(s)" of its monopolization claim. Judge Lifland concluded in 2000 that Purepac had stated a claim that entitled it to the relief sought and denied Warner-Lambert's motion to dismiss Purepac's antitrust and New Jersey common-law unfair-competition counterclaims. *See Warner-Lambert Co. v. Purepac Pharm. Co.*, Nos. 98-2749, 99-5948 & 00-2053, 2000 WL 34213890 (D.N.J. Dec. 22, 2000). Warner-Lambert's motion to dismiss rehashes many arguments that Judge Lifland already rejected.[4] Warner-Lambert essentially has filed a premature summary-judgment motion, disputing the material facts alleged in Purepac's counterclaim. Its motion should therefore be denied.

II. Purepac Pleads a Sufficient Unclean-Hands Defense and Counterclaim

Warner-Lambert seeks an injunction preventing Purepac from selling "any gabapentin product." (Compl. ¶ 32.) A court should issue an injunction in accordance with the principles of equity. 35 U.S.C. § 283; *Lewis v. Hyland*, 554 F.2d 93, 102 (3d Cir. 1977). An unclean-hands

[4] The Court should decline Warner-Lambert's request to revisit Rule 12(b)(6) questions that Judge Lifland already decided in denying Warner-Lambert's motion to dismiss in 2000. *See, e.g., In re Mercedes-Benz Antitrust Litig.*, 364 F. Supp. 2d 468, 475-76 (D.N.J. 2005).

defense can defeat injunctive relief. *The Original Great Am. Chocolate Chip Cookie Co. v. River Valley Cookies, Ltd.*, 970 F.2d 273, 281-82 (7th Cir. 1992).

Warner-Lambert argues that Purepac's unclean-hands allegations do not suffice since Warner-Lambert's illegal marketing activities are not "closely connected" to the '482 patent's prosecution or enforcement. (Pls.' Br. 14-18.) Warner-Lambert also argues that its illegal marketing activities ended before the '482 patent issued and, therefore, do not give rise to Warner-Lambert's right to sue for infringement. (Pls.' Br. 18-19.) But Warner-Lambert's arguments lack merit.

A. Warner-Lambert's Illegal Marketing Activities Relate Directly to Warner-Lambert's Effort to Enforce the '482 Patent

The unclean-hands doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 599 (3d Cir. 1972). A court has broad discretion to refuse to aid the unclean litigant. *Id*. Accordingly, "[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim." *Id*.

Purepac's allegations satisfy this standard because Warner-Lambert's fraudulent marketing practices relate directly to Warner-Lambert's effort to enjoin Purepac from selling gabapentin products for, among other things, the off-label uses that Warner-Lambert targeted with its illegal scheme to boost Neurontin's sales. The following allegations, which the Court must accept as true, establish the necessary connectedness.

Once the FDA approves a drug product for a particular use, a manufacturer may not market or promote that product for other unapproved uses. (Defenses ¶ 10.) In other words, a company may not promote off-label uses. (*Id.* ¶ 10.) A physician, however, may prescribe a

drug product for an off-label use. (*Id.* ¶ 10.) The FDA approved Neurontin capsules solely for adjunctive or supplemental use in treating epilepsy. (*Id.* ¶ 11.) The FDA later approved Neurontin tablets for adjunctive or supplemental use in treating epilepsy. (*Id.* ¶ 11.) But Warner-Lambert aggressively marketed Neurontin for numerous off-label uses. (*Id.* ¶ 11.)

Warner-Lambert's aggressive marketing techniques included, for example (a) disseminating false information about Neurontin's effectiveness for treating various indications, (b) suppressing negative information concerning Neurontin's effectiveness, (c) having sales representatives extol Neurontin's virtues as a monotherapy even though the FDA had not approved it as a monotherapy, and (d) offering kickbacks to doctors to support certain off-label uses despite the void in scientific literature to support those uses. (*Id.* ¶¶ 11-20.) Indeed, as a result of these illegal activities, Warner-Lambert pleaded guilty to criminal health-care fraud and paid more than $430 million to resolve its criminal and civil liabilities. (*Id.* ¶ 25.)

Warner-Lambert's marketing scheme caused Neurontin's sales for certain off-label uses to balloon, e.g., for (a) all types of neuropathic pain, (b) nociceptive and non-neuropathic pain, (c) restless leg syndrome/periodic limb movement disorder, (d) bipolar and other mood disorders, (e) anxiety disorders, (f) monotherapy for epilepsy, and (g) migraines and other forms of headaches. (*Id.* ¶¶ 11-12, 27-28.) Judge Saris has recognized that Warner-Lambert illegally promoted Neurontin for these off-label uses. *See In re Neurontin Mktg. & Sales Practices Litig.*, 244 F.R.D. 89, 92-93 (D. Mass. 2007). Warner-Lambert's illegal promotion of Neurontin caused sales for off-label uses to dwarf sales for the approved use. (Defenses ¶¶ 27-28.)

Thus, Warner-Lambert illegally created and maintained the market for various off-label uses of Neurontin. Here, Warner-Lambert does not limit its request for injunctive relief to Neurontin's approved uses. (Compl. ¶ 32.) Rather, Warner-Lambert requests an injunction forbidding Purepac from selling gabapentin products for all purposes, including the off-label

uses comprising the illegally created market. (*Id.* ¶ 32.) Accordingly, to the extent Warner-Lambert seeks to enjoin Purepac from selling gabapentin products for off-label uses, Warner-Lambert's pursuit of injunctive relief relates directly to its illegal marketing activities.

Purepac has alleged facts regarding Warner-Lambert's unclean hands that—if proven—would entitle it to relief, e.g., a declaration precluding the '482 patent's enforcement. The Court should therefore deny Warner-Lambert's motion to dismiss so as not to become an "abettor of [Warner-Lambert's] iniquity." *Monsanto*, 456 F.2d at 598.

In arguing that its illegal activities do not bear enough of a connection to this action, Warner-Lambert relies on Judge Chelser's December 2000 denial of Purepac's motion to compel. (Pls.' Br. 16.) Warner-Lambert misplaces its reliance on Judge Chesler's ruling.

First, Purepac appealed Judge Chesler's ruling under Rule 72(a) to Judge Lifland, but Judge Lifland never decided Purepac's appeal. When Judge Lifland did consider Purepac's unclean-hands allegations in connection with Warner-Lambert's motion for a preliminary injunction against Purepac, he relied in part on those allegations to deny the motion. He said, "I am not persuaded that today's Neurontin market, largely made up of off-label uses, is totally unaffected by admitted off-label promotion efforts . . . ." (Amundson Decl. Ex. 6 at 24-25.)

Second, with all due respect to Judge Chesler, he wrongly decided the issue. Put simply, he had to decide whether documents relating to Warner-Lambert's illegal marketing activities were relevant to Purepac's unclean-hands defense to the '479 patent. The '479 patent recites a method of using gabapentin to treat neurodegenerative diseases. Although the FDA only approved Neurontin as adjunctive therapy for epilepsy, Warner-Lambert actively and illegally promoted Neurontin for non-epilepsy uses. (Defenses ¶ 11.) As Purepac argued then, those off-label uses—and Warner-Lambert's efforts to create the market for them—related to Warner-Lambert's request for injunctive relief. Here, if the Court determines that Warner-Lambert

illegally created a large part of the gabapentin market, the Court should preclude Warner-Lambert from benefiting from its unlawful conduct. *See Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 670 (1944).

Moreover, Judge Chesler decided the issue in December 2000 without the benefit of all the facts, including Warner-Lambert's guilty plea to illegal marketing. (Defenses ¶ 25.) With the benefit of a fuller record, Judge Chesler, like Judge Lifland in October 2004, would likely have decided the issue in Purepac's favor.

Warner-Lambert contends that *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co.*, 747 F.3d 844 (3rd Cir. 1984), supports its position that its illegal marketing activities provide no basis for an unclean-hands defense since they do not relate to the subject matter of Warner-Lambert's infringement claim. (Pls.' Br. 17.) Warner-Lambert misplaces its reliance on *Ciba-Geigy*.

There, Ciba sued Bolar for unprivileged imitation and passing off under the Lanham Act and New Jersey law. 747 F.3d at 849. Both federal law and New Jersey law required Ciba to prove the following elements of unprivileged imitation (a) Bolar imitated a nonfunctional feature of Ciba's product, (b) the imitation caused confusion as to the product's origin, and (c) the product had acquired secondary meaning. *Id*. at 850. To prove passing off, Ciba had to show that Bolar marketed a product to pharmacists in a form in which Bolar could "reasonably anticipate that it may be passed off as another product." *Id*. at 852.

Bolar's unclean-hands defense consisted of three allegations: (a) Ciba marketed its product as a "step-two" drug rather than a "step-three" drug, (b) Ciba sold two adulterated batches of its product in 1976, and (c) the markings on Ciba's product did not satisfy FDA standards. *Id*. at 855. The Third Circuit rejected Bolar's unclean-hands defense because Ciba's improper conduct did not relate to its claims against Bolar. *Id*.

By contrast, Warner-Lambert's illegal marketing activities relate directly to its attempt to enforce the '482 patent through an injunction barring sales. Warner-Lambert asks the Court to permanently enjoin Purepac from selling gabapentin products for all uses, including the off-label uses at the heart of Warner-Lambert's unlawful scheme. (Compl. ¶ 32.) Since Warner-Lambert seeks to enjoin Purepac from selling gabapentin products for off-label uses, Warner-Lambert's pursuit of injunctive relief relates to the illegal marketing activities that created and expanded the market for off-label uses. Thus, the Court should deny Warner-Lambert's motion to dismiss Purepac's unclean-hands defense and counterclaim.

B. Warner-Lambert's Illegal Conduct Continued After Patent Issuance and the Effects of Warner-Lambert's Illegal Conduct Persist to This Day

Warner-Lambert contends that its illegal conduct ended before the '482 patent issued and does not give rise to Warner-Lambert's right to sue for infringement. (Pls.' Br. 18-19.) This contention misses the mark since Warner-Lambert's illegal conduct relates directly to Warner-Lambert's effort to enforce the '482 patent by securing an injunction barring sales for off-label uses. This contention also creates a factual dispute. Purepac did not—and does not—concede that Warner-Lambert's illegal conduct ended before the '482 patent issued. Instead, Purepac maintains that Warner-Lambert's illegal conduct continued after the '482 patent issued. And as discussed below, Purepac has evidence to support this.

Regardless of when Warner-Lambert's illegal marketing activities ended, those activities produced effects that persist to this day. (Defenses ¶¶ 23, 26.) Warner-Lambert's misconduct continues to expose doctors, and by natural progression the public at large, to inaccurate and materially incomplete information about Neurontin's efficacy for unproven uses, e.g., due to Warner-Lambert's suppression of negative or unfavorable studies, evidence, and data. (*Id.* ¶¶ 23, 26.) These factual allegations, which the Court must accept as true, establish a right to

relief beyond a speculative level. *See Phillips*, 515 F.3d at 233-34.

While purging the activity constituting unclean hands may restore a patentee's rights, such purging only occurs "upon abandonment of the abusive practice and dissipation of any harmful consequences." 6 Donald S. Chisum, *Chisum on Patents* § 19.04 (2005). Warner-Lambert's wrongful activities still taint the medical profession with inaccurate and incomplete information about Neurontin. Thus, the harmful consequences have not dissipated, and Warner-Lambert cannot satisfy the purge standard.

Although Warner-Lambert contends that its illegal conduct ended before the '482 patent issued, the facts indicate otherwise. Among other things, Warner-Lambert sponsored journal articles in 2002 and 2003 that promoted Neurontin for off-label uses, such as diabetic peripheral neuropathy and neuropathic pain. (Amundson Decl. Exs. 7-10; Ex. 11 ¶¶ 44, 121-31, 256-74.) In addition, Warner-Lambert's marketing efforts after the '482 patent issued included the dissemination of false statements to doctors for the purpose of increasing Neurontin's sales. (Amundson Decl. Ex. 11 ¶¶ 45-46, 82, 150-53, 169-71, 275-90.)

In short, Warner-Lambert's contention that its illegal marketing activities ended before the '482 patent issued creates a factual issue inappropriate for resolution under Rule 12(b)(6).

III. Purepac Pleads a Sufficient Patent-Misuse Defense and Counterclaim

Warner-Lambert contends that Purepac has failed to state a patent-misuse defense because Purepac has not alleged that Warner-Lambert extended the '482 patent's temporal scope. (Pls.' Br. 21.) Warner-Lambert's contention lacks merit.

A party engages in patent misuse by attempting to broaden the physical or temporal scope of the patent for anticompetitive purposes. *See, e.g., Windsurfing Int'l, Inc. v. AMF Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1985). Patent misuse "arose to restrain practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus

were deemed contrary to public policy." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) (citation omitted).

The intentional delay of patent issuance exists as one type of impermissible broadening of the temporal scope of a patent. In *Woodbridge v. United States*, William Woodbridge intentionally delayed the issuance of a patent directed to cannon projectiles for over nine years for the "purpose of making the term of the monopoly square with the period when the commercial profit from it would be highest." 263 U.S. 50, 56 (1923). The Supreme Court held that Woodbridge forfeited the patent right by deliberately "postpon[ing] the term of the patent the inventor always intended to secure." *Id*. at 59.

Here, Warner-Lambert (a) breached its duty of candor during the '482 patent's prosecution, (b) improperly delayed the '482 patent's issuance, and (c) wrongly extended the '482 patent's temporal scope. (Defenses ¶¶ 30-42.) Warner-Lambert accomplished this goal by intentionally failing to inform the Patent Office of one of its own gabapentin patents—U.S. Patent No. 4,152,326—for several years and not until after the Patent Office had actually allowed the application and assigned a patent number. (*Id.* ¶¶ 30-42.) At the time of Warner-Lambert's intentional withholding of the '326 patent, only a handful of gabapentin patents existed, and they all belonged to Warner-Lambert. (*Id.* ¶ 33.)

Warner-Lambert's delay in obtaining the '482 patent and its belated infringement suit enabled it to forestall competition from generic gabapentin products much longer than it could have but for its improper prosecution delay. (*Id.* ¶¶ 30, 41.) Warner-Lambert's improper postponement of the '482 patent's issuance—and therefore of the '482 patent's expiration—renders the patent unenforceable. *See Woodbridge*, 263 U.S. at 63.

Warner-Lambert ignores *Woodbridge* and instead cites *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979), and *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869

(Fed. Cir. 1997). (Pls.' Br. 21 n.8.) Warner-Lambert cites these cases for the proposition that the temporal expansion of a patent primarily involves situations where the patentee negotiates with the leverage of the patent monopoly and uses that leverage to obtain royalties beyond patent expiration. (Pls.' Br. 21 n.8.) Because Warner-Lambert did not collect post-expiration royalties, Warner-Lambert suggests that it did not extend the '482 patent's temporal scope. (Pls.' Br. 21.)

But *Aronson* and *Virginia Panel* merely exemplify situations involving patent misuse through temporal-scope extensions. They do not exhaust or restrict patent misuse through temporal-scope extensions to those particular situations. *See Woodbridge*, 263 U.S. at 63. Here, Warner-Lambert misused the '482 patent by deliberately and wrongly delaying its issuance and its expiration for anticompetitive purposes. (Defenses ¶¶ 30-42; Countercl. ¶¶ 104-122.) This delay extended the '482 patent's temporal scope. Hence, Purepac has alleged facts relating to Warner-Lambert's patent misuse that—if proven—would entitle it to relief, e.g., a declaration precluding the '482 patent's enforcement. Accordingly, the Court should deny Warner-Lambert's motion to dismiss Purepac's patent-misuse defense and counterclaim.

IV. Unclean Hands and Patent Misuse May Form the Bases of Counterclaims Seeking Declaratory Relief

Warner-Lambert wrongly contends that the law recognizes unclean hands and patent misuse as affirmative defenses but not counterclaims. (Pls.' Br. 23-24.) Purepac's unclean-hands and patent-misuse counterclaims request relief under the Declaratory Judgment Act, i.e., a declaration precluding the '482 patent's enforcement. That statute provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201.

Recently, in *MedImmune, Inc. v. Genentech, Inc*., the Supreme Court clarified the

standard for pleading a declaratory-judgment claim. 127 S. Ct. 764, 771 (2007). The Court ruled that the dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests" and must be "real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id*.

Purepac's pleading defines the factual and legal dimensions of its unclean-hands and patent-misuse counterclaims. Warner-Lambert does not—and cannot—dispute that the parties have adverse legal interests. Warner-Lambert accuses Purepac of infringing the '482 patent and seeks damages and an injunction. (Compl. ¶¶ 20-32.) Purepac denies Warner-Lambert's infringement allegations and further pleads facts to establish invalidity and unenforceability, e.g., that Warner-Lambert's illegal marketing activities render enforcement of the '482 patent improper under the principles of equity. This dispute certainly rises to "definite and concrete." *See MedImmune*, 127 S. Ct. at 771.

Moreover, Purepac's unclean-hands and patent-misuse counterclaims "admit of specific relief through a decree of a conclusive character," i.e., a decree preventing Warner-Lambert from enforcing the '482 patent. *Id*. Purepac's unclean-hands and patent-misuse counterclaims satisfy the standard for a declaratory judgment. Consequently, the Court should deny Warner-Lambert's motion to dismiss these counterclaims.

Consistent with *MedImmune*, the Federal Circuit has acknowledged patent misuse as a proper basis for a declaratory-judgment claim. For example, in *Glitsch, Inc. v. Koch Engineering Co.*, the Federal Circuit noted that the Supreme Court's decision in *Mercoid* "makes clear that a party that did not raise the issue of patent misuse in one action may raise that issue in another action based on a separate assertion of infringement, whether as a defense against the claim of infringement **or in a request for declaratory relief**." *Glitsch*, 216 F.3d 1382, 1386

(Fed. Cir. 2000) (emphasis added). Accordingly, Purepac's allegations of unclean hands and patent misuse may properly form the bases of counterclaims seeking declaratory relief under the Declaratory Judgment Act.

Warner-Lambert relies on *Aptix Corp. v. Quickturn Design Systems, Inc*., 269 F.3d 1369 (Fed. Cir. 2001), and *B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419 (Fed. Cir. 1997), to support its argument that the law recognizes unclean hands and patent misuse as affirmative defenses but not counterclaims. Warner-Lambert mischaracterizes the law.

In *Aptix*, the district court declared the patent at issue unenforceable because *Aptix* submitted multiple falsified engineering notebooks to the court. 269 F.3d at 1371. The Federal Circuit held, however, that "[l]itigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, or even affect, the original grant of the property right." *Id*. at 1375. That holding addressed litigation misconduct, which concerned the integrity of the judicial process rather than the relief requested by the patentee. That holding does not extend as far as Warner-Lambert urges to bar an unclean-hands counterclaim where, as here, the patentee's misconduct relates directly to the relief requested by the patentee.

In *Braun*, the Federal Circuit held that patent misuse simply renders a patent unenforceable and provides no basis for seeking monetary relief. 124 F.3d at 1428. That holding does not bar a patent-misuse counterclaim seeking declaratory relief, i.e., a declaration precluding a patent's enforcement. *Id.* Notably, Warner-Lambert quotes the Federal Circuit's summary of Braun's argument, not the court's holding. (Pls.' Br. 23-24.) Like *Aptix*, *Braun* does not extend as far as Warner-Lambert urges.

Other courts have rejected arguments like Warner-Lambert's. In *Linzer Products Corp. v. Sekar*, for example, Linzer asserted patent misuse as an independent cause of action, and Sekar moved to dismiss Linzer's patent-misuse claim. 499 F. Supp. 2d 540, 552-53 (S.D.N.Y. 2007).

In denying Sekar's motion, the district court noted that the Federal Circuit in *Braun* held only that "a plaintiff may not recover **damages** when seeking a declaratory judgment of patent misuse." *Id*. at 553 (emphasis added). The court observed that "*Braun* did not proscribe seeking a declaratory judgment of patent misuse. Indeed, in later actions, the Federal Circuit has allowed such claims without comment." *Id*. (citing *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001); *Competitive Techs., Inc. v. Fujitsu Ltd*., 374 F.3d 1098, 1101 (Fed. Cir. 2004)); *see also Marchon Eyewear, Inc. v. Tura LP*, No. 98 CV 1932, 2002 WL 31253199, at *9 (E.D.N.Y. Sept. 30, 2002) (rejecting argument that *Braun* proscribes patent-misuse claims).

In summary, the Court should deny Warner-Lambert's motion to dismiss Purepac's unclean-hands and patent-misuse counterclaims because they properly state claims upon which the Court may grant declaratory relief under the Declaratory Judgment Act.

V. Purepac States a Claim by Alleging an Overall Scheme to Monopolize

Purepac has alleged in detail how Warner-Lambert engaged in a comprehensive multi-faceted scheme to monopolize the market for gabapentin anhydrous. Warner-Lambert's motion compartmentalizes Purepac's allegations into three separate anticompetitive acts, arguing that each individual act is not actionable. (Pls.' Br. 28-46.) That is improper. The anticompetitive effects and legality of the alleged monopolization scheme must be evaluated as a whole.

As the Court recognized in *In re Remeron Antitrust Litigation*:

> [T]he relevant inquiry is the anticompetitive effect of the defendant's exclusionary practices considered together . . . courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation.

335 F. Supp. 2d 522, 528 (D.N.J. 2004) (Hochberg, J.) (quoting *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003)). In *Continental Ore*, the Supreme Court made it clear that a claimant's allegations of exclusionary conduct "should be given the full benefit of their proof without

tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." 370 U.S. at 699.[5] Warner-Lambert seeks to overturn this settled principle.

Warner-Lambert's monopolization scheme is not protected by *Noerr-Pennington*. In *California Motor Transport Co. v. Trucking Unlimited*, the Supreme Court held:

> [A] pattern of baseless repetitive claims may emerge which leads the fact-finder to conclude that the administrative and judicial processes have been abused. . . . [A]ctions of that kind cannot acquire immunity by seeking refuge under the umbrella of "political expression."

404 U.S. 508, 513 (1972). As the Federal Trade Commission explained in *In re Bristol-Myers Squibb Co*., this reasoning also applies in cases like this one, involving systematic abuse of the Hatch-Waxman regulatory framework:

> [T]he logic and policy underlying the Supreme Court's decision in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), which held a pattern of filings undertaken without regard to their merits to be outside the protections of *Noerr*, supports the application of a pattern exception for BMS's alleged pattern of conduct across its buspirone, paclitaxel, and cisplatin products, and thus provides a separate reason to reject *Noerr* immunity here. . . . the overall course of conduct challenged here constitutes a clear and systematic pattern of anticompetitive misuse of governmental processes, that is, abusive filings undertaken without regard to the merits, in order to use administrative and judicial processes - rather than the outcome of those processes - as a weapon to obstruct competition. Just as the repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of *Noerr* immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of *Noerr's* protection.

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[5] *See also United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 44 (D.D.C. 2000) ("[O]nly when the separate categories of conduct are viewed, as they should be, as a single, well-coordinated course of action does the full extent of the violence that Microsoft has done to the competitive process reveal itself"); *Aspen Highland Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1522 n.18 (10th Cir. 1984), *aff'd*, 472 U.S. 585 (1985) (holding that it was not necessary for plaintiff to prove that each allegedly anticompetitive act was itself sufficient to support the monopolization claim).

Analysis to Aid Public Comment at 11, *In re Bristol-Myers Squibb Co.*, No. C-4076 (F.T.C. Mar. 7, 2003), *available at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm.

Even if some of the components of Warner-Lambert's monopolization scheme, standing alone, would qualify for *Noerr-Pennington* immunity (which they do not), it would be "error for the court to treat the *Noerr-Pennington* doctrine as a rule of evidence that forbids the introduction of evidence . . . relating to efforts to obtain governmental protection to show an antitrust violation."[6] *In re Cardizem CD Antitrust Litig*., 105 F. Supp. 2d 618, 645 (E.D. Mich. 2000) (citing *In re Brand Name Prescription Drugs Antitrust Litig*., 186 F.3d 781, 789 (7th Cir. 1999)) (internal quotations omitted); *see also ID Sec. Sys. Can., Inc. v. Checkpoint Sys., Inc.*, 249 F. Supp. 2d 622, 656 (E.D. Pa. 2003) (allowing evidence of patent litigation as proof of an overall monopolization scheme even though the litigation itself was not alleged to be sham), *vacated in part on other grounds*, 268 F. Supp. 2d 448 (E.D. Pa. 2003); *Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d 750, 764 (D.N.J. 1999) (holding that Biovail's lack of standing to enforce the FTC Decree "does not mean that defendants' behavior with respect to the FTC Decree cannot be considered . . . as support for Biovail's antitrust claims.").[7]

Indeed, in *Remeron*, the Court denied a motion to dismiss allegations of an overall monopolization scheme in the Hatch-Waxman context on this very basis. The plaintiffs in that

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[6] Similarly, even if the Court were to agree with Warner-Lambert that its actions before the Patent Office and its lawsuits against Purepac are *Noerr-Pennington* protected, the remaining components of Warner-Lambert's monopolization scheme (the fraudulent Orange Book submissions) still independently state a claim upon which relief can be granted.

[7] *See also Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) ("Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts relied upon to effectuate the conspiracy the [Sherman Act] forbids, they come within its prohibition"); *Alpha Lyracom Space Commc'ns v. Commc'ns Satellite Corp*., No. 89 Civ. 5021, 1993 WL 97313, at *5 (S.D.N.Y. Mar. 30, 1993) ("[W]holly innocent acts if they are part or in furtherance of an overall plan to monopolize . . . become unlawful") (internal quotations and citations omitted).

case alleged an "overall scheme to monopolize the relevant market, claiming that when taken together, the allegations against Organon constitute an antitrust violation, even if the individual allegations are found to not violate antitrust laws," which was upheld by the Court despite Organon's claims of *Noerr-Pennington* immunity for certain of the individual allegations. *Remeron*, 335 F. Supp. 2d at 526.[8] Here, as in *Remeron*, "[b]ecause [Purepac's] overall scheme [to monopolize] claim rest[s] upon determinations that flow from factual allegations, this Court [should] reserve judgment on this issue at this stage of the litigation." 335 F. Supp. 2d at 528 (citations and internal quotations omitted).

None of the opinions cited by Warner-Lambert considered Warner-Lambert's various anticompetitive acts in the context of the overall monopolization scheme that Purepac has alleged. (Pls.' Br. 39-46.) Indeed, after Judge Lifland denied Warner-Lambert's motion to dismiss Purepac's antitrust counterclaims in December 2000, those claims were stayed both in *Warner-Lambert v. Purepac* (2000 WL 34213890, at *12-13) and in this action—until the Court lifted the stay in this action on February 27, 2008 (Amundson Decl. Ex. 12).

A. Warner-Lambert Abused Patent Office Process to Gain an Additional 30-Month Stay Under the Hatch-Waxman Act

Purepac has alleged in detail how, as part of its monopolization scheme, Warner-Lambert abused Patent Office process during the '482 patent's prosecution to abuse the FDA's Hatch-Waxman rules and regulations. Warner-Lambert argues that this allegation fails to state a claim because Purepac has not alleged a *Walker Process* claim of fraud on the Patent Office. (Pls.' Br. 29-30.) Warner-Lambert's argument fails for a number of reasons.

[8] That is consistent with what other courts have done in the Hatch-Waxman context. *See, e.g.*, *Biovail*, 49 F. Supp. 2d at 762 ("[T]his court will . . . evaluate each allegation in the context of the antitrust claims as a whole"); *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (evaluating anticompetitive acts as "part of a larger scheme to maintain its monopoly in the market.").

First, Warner-Lambert mischaracterizes Purepac's allegations by addressing them in a vacuum. As discussed above, Warner-Lambert's abuse of Patent Office process should not be evaluated in isolation but rather in the context of Warner-Lambert's overall monopolization scheme. *See Remeron*, 335 F. Supp. 2d at 526, 528 (denying motion to dismiss claim alleging overall scheme to monopolize despite the defendant's assertion of *Noerr-Pennington* immunity for conduct before the Patent Office).

Second, Warner-Lambert misplaces its reliance on *Noerr-Pennington*. To be clear, Purepac does not assert in its antitrust counterclaims that the '482 patent should not have issued because of fraud on the Patent Office. Rather, Purepac takes issue with Warner-Lambert's abuse of Patent Office process to cause the '482 to issue in 2000 instead of 1995 for the purpose of triggering a second 30-month stay of FDA approval and extending Warner-Lambert's monopoly.

Such abuse of government process is not protected petitioning activity. *Noerr-Pennington* does not protect the use of "governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *New York Jets, LLC v. Cablevision Sys. Corp.*, No. 05-2875, 2005 WL 3454652, at *3 (S.D.N.Y. Dec. 19, 2005) (denying motion to dismiss sham-petitioning claim because petitions were allegedly not aimed at procuring a favorable outcome but were "intended to harass a competitor by imposing expense and delay") (citing *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991)); *see also Premier Elec. Constr. Co. v. Nat. Elec. Contractors Ass'n*, 814 F.2d 358, 376 (7th Cir. 1987) (Easterbrook, J.). Indeed, in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, the Supreme Court acknowledged that "the far-reaching social and economic consequences of a patent" make it important "that patent monopolies spring from backgrounds free from fraud or **other inequitable conduct** and that such monopolies are kept within their legitimate scope." 382 U.S. 172, 177 (1965) (emphasis added).

The anticompetitive effects Purepac has alleged resulted purely from the abuse of the process and inequitable conduct before the Patent Office—withholding prior art, withdrawal of a patent application, and filing an unnecessary continuation application—not from Warner-Lambert's pursuit of the '482 patent or the Patent Office's resulting issuance of that patent. But for Warner-Lambert's wrongful conduct before the Patent Office, Warner-Lambert would not have gained the second automatic 30-month stay under the Hatch-Waxman Act.[9]

Indeed, abuse of process and inequitable conduct before the Patent Office identical to those Purepac has alleged here have been found to state a claim for monopolization before. In *DiscoVision Associates v. Disc Manufacturing, Inc.*, the court denied a motion to dismiss Disc Manufacturing's monopolization claim based on, among other things, the allegation that DiscoVision "abus[ed] the Patent and Trademark Office's [ ] continuation application provisions and/or employ[ed] improper delaying tactics in the Patent Office" by "purposefully withhold[ing] material prior art and mak[ing] intentional misrepresentations to the PTO." Nos. 95-21 & 95-345, 1997 WL 309499, at *3, *13 (D. Del. Apr. 3, 1997). The court rejected

[9] Warner-Lambert's reliance on *Noerr-Pennington* is also inappropriate because its patent withdrawal and continuation application were not government petitioning protected by *Noerr-Pennington*. Although a withdrawal and continuation application like the one Warner-Lambert submitted in January 1995 technically was a petition (*see* 37 C.F.R. § 1.313(b)(5) (1995)), as a practical matter, it sought nothing more than a rubber stamp from the Patent Office because—as Warner-Lambert well knew—no reasonable examiner would deny a petition allegedly seeking to ensure compliance with the duty of disclosure (*see* 37 C.F.R. § 1.56 (1995)) through the filing of an information disclosure statement (Countercl. ¶¶ 106, 109-10). *See Manual of Patent Examining Procedure* § 2001.04 (6th ed. 1995) (explaining that the duty of disclosure is critical in ensuring that the Patent Office fulfills its "obligation not to unjustly issue patents and . . . unjustly deny patents."). Indeed, Warner-Lambert's "petition" was rubber-stamped by the Patent Office within two days. Accordingly, Warner-Lambert's 1995 application withdrawal and continuation application were no different from Orange Book listings or tariff filings. *See In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) ("[T]he FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing."); *Litton Sys., Inc. v. AT&T*, 700 F.2d 785, 807 (2d Cir. 1983) ("The decision to impose and maintain the interface tariff was made in the AT&T boardroom, not at the FCC.").

DiscoVision's argument that it lawfully exercised its rights under the patent laws and held that:

> [t]hese allegations, if true, are sufficient to support the inference that DiscoVision's continuation applications had an anticompetitive effect beyond the grant of the patent. Consequently, the court finds that DMI's allegations relating to DiscoVision's continuation applications may form a basis for antitrust liability.

Id. at *8. Here, too, Purepac alleged that Warner-Lambert's continuation applications, withholding of prior art, and withdrawal of the allowed application had an "anticompetitive effect beyond the grant of the ['482] patent," namely, a second automatic 30-month stay under the Hatch-Waxman Act at a time when generic entry would otherwise have occurred. (Countercl. ¶¶ 119-22.)

Similarly, in *Remeron*, the Court decided that intentional delay in listing a patent in the Orange Book to obtain benefits under the Hatch-Waxman Act can amount to monopolization. The Court reasoned that "if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market." 335 F. Supp. 2d at 532. The same rule should apply to Patent Office proceedings under the circumstances alleged here.

B. Warner-Lambert Knowingly Made False and Improper Orange Book Submissions Relating to the '476 Patent

Purepac has alleged that, as part of its overall monopolization scheme, Warner-Lambert fraudulently submitted the '476 patent for listing in the Orange Book. (Countercl. ¶¶ 123-35.) Warner-Lambert argues that this allegation fails to state a claim (a) due to lack of proximate cause, (b) because it is premised on an erroneous factual allegation, and (c) because the listing of the '476 patent was proper as a matter of law.

In arguing that it acted reasonably in listing the '476 patent in the Orange Book, Warner-Lambert rehashes arguments that it made when it moved to dismiss Purepac's antitrust

counterclaims in July 2000. (Amundson Decl. Ex. 13 at 10-12.) Judge Lifland already rejected those arguments and concluded that Purepac sufficiently pleaded fraudulent Orange Book submissions relating to the '476 patent. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *6. But Warner-Lambert's arguments are unavailing in any event.

As an initial matter, Warner-Lambert's arguments mischaracterize Purepac's allegations by addressing the Orange Book listings in isolation rather than as part of the alleged multi-faceted monopolization scheme. Warner-Lambert's proximate cause arguments also fail for that reason (*see*, *infra*, Section VI).

Warner-Lambert's assertion that Purepac's Orange Book listing allegations rest on factual errors is both inappropriate at this stage and irrelevant. (Pls.' Br. 33-36.) Warner-Lambert's contention that the '476 patent was listed in May 1994—even if true—makes no difference to Purepac's allegation that Warner-Lambert improperly listed the patent with an eye towards the '544 patent's potential expiration to allow Warner-Lambert to delay the '482 patent's issuance.

Warner-Lambert's argument that the listing of the '476 patent was proper as a matter of law is simply wrong. Purepac has alleged in detail how Warner-Lambert made Orange Book submissions relating to the '476 patent that were knowingly false and improper. While the '476 patent covers gabapentin **monohydrate**, Warner-Lambert declared to the FDA that it covered "a crystal form and the use of Neurontin," which is gabapentin **anhydrous**. (Countercl. ¶¶ 125-28.) Warner-Lambert always knew that the '476 patent did not cover Neurontin. (*Id.* ¶¶ 129-31, 141-47.) Indeed, before listing the '476 patent, Warner-Lambert had specifically represented as much to the Patent Office to obtain the '476 patent. (*Id.* ¶ 132.) Based on similar allegations, the court in *Buspirone* denied Bristol-Myers' motion to dismiss an antitrust claim alleging an improper Orange Book listing. Bristol-Myers had secured a method-of-use patent by

representing to the Patent Office that that patent did not cover an approved use of buspirone, but then turned around and listed that patent in the Orange Book as covering an approved use of buspirone. *See Buspirone*, 185 F. Supp. 2d at 375.

Warner-Lambert misplaces its reliance on *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*, 10 F. Supp. 2d 446 (D.N.J. 1998). There, the court considered "whether the Aredia drug substance covered by [Novartis'] '880 patent [was] a 'component' of the [FDA-approved] drug product within the meaning of the statute and the regulations, when it does not appear in the final [FDA-approved] product" but is used in the manufacture of the final FDA-approved product. *Id.* at 454. The court answered that question affirmatively. *Id.* at 458. In *Ben Venue*, there was "no dispute that the patented pentahydrate form of the Aredia drug substance [wa]s used in the manufacture of the [FDA-approved] Aredia drug-product." *Id.* In sharp contrast here, Purepac has specifically alleged that Warner-Lambert knew all along that the gabapentin monohydrate covered by the '476 patent is not a component of the FDA-approved gabapentin anhydrous sold as Neurontin. (Countercl. ¶¶ 129-32.)

Warner-Lambert's reliance on *Zenith Laboratories, Inc. v. Abbott Laboratories, Inc*. is equally unavailing. In fact, *Zenith* supports denial of Warner-Lambert's motion to dismiss. Zenith alleged that Abbott improperly listed the patent at issue because it covered anhydrous forms of terazosin hydrochloride, while the FDA-approved product (Hytrin) only covered terazosin hydrochloride in dihydrate form. Abbott countered that "although the different polymorphs of terazosin hydrochloride represent different structural arrangements of that compound, they are all essentially the same thing, namely the drug substance terazosin hydrochloride," so that listing of the patent covering the anhydrous form was proper. No. 96-1661, 1997 U.S. Dist. LEXIS 23954, at *16 (D.N.J. Oct. 1, 1997). The Court denied Abbott's motion to dismiss Zenith's claim due to the following material factual dispute:

> [D]ifferent polymorphic forms containing the same active ingredient **may** be considered by the FDA as equivalents. However, this is the case **only if the dissolution, solubility and absorption of the polymorphs are the same**. It is not clear that these factors are consistent as between Hytrin and the later patents.

Id. at *8 (emphasis added). Here, Purepac has alleged that Warner-Lambert knew that the "the dissolution, solubility and absorption" (*id.*) of the monohydrate covered by the '476 patent and gabapentin anhydrous are not the same. (Countercl. ¶¶ 129-32.)

Similarly, nothing in the FDA's 2003 statement that Warner-Lambert relies on establishes as a matter of law that there was a reasonable basis for Warner-Lambert's Orange Book submission of the '476 patent. In that policy statement, the FDA merely stated that "there **may have been some** legitimate confusion regarding [its] prior position concerning submission of such patents for listing." 68 Fed. Reg. 36,676, 36,678 (June 18, 2003) (emphasis added). Significantly, the words "such patents" in that statement referred only to patents covering a polymorph that is "the 'same' active ingredient (i.e., that a drug product containing the polymorph will perform the same as the drug product described in the NDA with respect to such characteristics as dissolution, solubility, and bioavailability)." *Id.* Purepac has alleged that Warner-Lambert knew that (a drug product containing) gabapentin monohydrate does not "perform the same as" Neurontin "with respect to such characteristics as dissolution, solubility, and bioavailability." (Countercl. ¶¶ 127-32.) In fact, Warner-Lambert knew that gabapentin monohydrate was unsuitable and would not perform the same as gabapentin anhydrous in capsule formulations. (*Id.* ¶¶ 129-30; Suppl. Amundson Decl. Ex. 17, 4/3/89 Letter at 2, 3.)

Furthermore, because *Noerr-Pennington* does not protect Orange Book submissions, the reasonableness of the '476 patent listing cannot be established as a matter of law based on a general statement by the FDA that "there may have been some legitimate confusion [about

listing polymorph patents]," without determining if Warner-Lambert was in fact "legitimate[ly] confus[ed]" as to the '476 patent listing. That is a disputed fact. (Countercl. ¶¶ 141-47.)

C. Warner-Lambert Knowingly Made False and Improper Orange Book Submissions Relating to the '479 Patent

Purepac has alleged that, as part of its overall monopolization scheme, Warner-Lambert also fraudulently listed the '479 patent in the Orange Book. (Countercl. ¶¶ 136-40.) As with the '476 patent listing, Warner-Lambert argues that that the listing of the '479 patent (a) is not proximately related to any harm suffered by Purepac, (b) rests on erroneous factual allegations, and (c) was proper as a matter of law. (Pls.' Br. 31-38.) (The first and second arguments are addressed in Sections VI and V(B), respectively.) Warner-Lambert reargues issues that Judge Lifland already decided. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *6 (holding that Purepac has adequately alleged that "Warner-Lambert knowingly made misrepresentations to the FDA"). Warner-Lambert's arguments mischaracterize Purepac's monopolization claim by compartmentalizing Purepac's allegations. Warner-Lambert's arguments fail in any event.

Warner-Lambert's Orange Book submissions for the '479 patent were knowingly false and improper. As the D.C. Circuit observed, in submitting Orange Book declarations for the '479 patent, "[Warner-Lambert] had chosen to ignore the regulations" that only permitted the listing of patents covering approved methods of use. *Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 884 (D.C. Cir. 2004). Indeed, Warner-Lambert later admitted as much, stating that it disagreed with those regulations. *See id.* at 885.

Of course, in submitting its declarations for the '479 patent, Warner-Lambert never disclosed its disagreement to the FDA. Warner-Lambert did disclose in its Orange Book submissions that the '479 patent covered the treatment of neurodegenerative diseases (an unapproved use), but only because it knew full well that that would go unnoticed since "the FDA

simply lists the patent information that it receives . . . expecting the [submitting party] to understand and abide by the regulatory mandates." *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 196 (D.D.C. 2002). By purposely submitting declarations for a patent covering an unapproved use, while knowing that the FDA would accept that declaration assuming—per 21 C.F.R. § 314.53(b)—that it would only include patents covering approved uses, Warner-Lambert fraudulently caused the '479 patent to be listed. Warner-Lambert thus engaged in a well-recognized abuse:

> [T]he [FDA's] much-touted "purely ministerial" role in the publication process, along with its policy of deferring to the representations of NDA holders about the scope of their patents, make it entirely possible that a brand manufacturer could submit a patent for publication (and see it published) without believing or averring that it actually covered an approved use.

Purepac v. Thompson, 238 F. Supp. 2d at 208 (citing *AAIPharma, Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002) for the proposition that "NDA holders can abuse the Orange Book listing process in the absence of any serious agency enforcement mechanism").

With a full record, Purepac will prove, based on Warner-Lambert's own research regarding Neurontin's efficacy for treating neurodegenerative diseases (Defenses ¶ 22), that Warner-Lambert knew that "a claim of patent infringement [of the '479 patent] could [not] reasonably be asserted" (21 U.S.C. § 355(b)) against a drug company wanting to market a generic gabapentin product. *See Buspirone*, 185 F. Supp. 2d at 375 (denying motion to dismiss antitrust claim based on improper listing where NDA holder had allegedly misrepresented to the FDA that an infringement claim could reasonably be asserted).

Warner-Lambert argues that the Court's opinion in *Organon, Inc. v. Mylan Pharmaceuticals, Inc.*, 293 F. Supp. 2d 453 (D.N.J. 2003), establishes as a matter of law that Warner-Lambert properly listed the '479 patent. Warner-Lambert is wrong. In *Organon*, the

Court relied on Judge Schall's concurring opinion in *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), to conclude that "it was [] reasonable for Organon" to have read the language "other conditions of use of a pending or approved application" in 21 C.F.R. § 314.53(b) to permit Orange Book listing of Organon's '099 patent, which the Court found covered an off-label use of Remeron. *Organon*, 293 F. Supp. 2d at 460 n.7. Purepac respectfully submits that Judge Schall misinterpreted 21 C.F.R. § 314.53(b). The "other conditions of use," as Warner-Lambert well knows, is a term of art in the FDA context that refers to the labeling in a new drug application (e.g., warnings, dosage instructions, etc.), not to an off-label use of the drug. *See, e.g.*, 21 U.S.C. § 355(d)(5) ("[C]onditions of use prescribed, recommended, or suggested in the proposed labeling thereof."); 21 C.F.R. § 314.125 (same).

In any event, even accepting Judge Schall's interpretation of 21 C.F.R. § 314.53(b), *Organon* differs from this case. First, unlike here, in *Organon* the Court evaluated an Orange Book listing claim in isolation rather than as part of an overall monopolization scheme. *See* 293 F. Supp. 2d at 456. Second, while Organon perhaps reasonably misinterpreted the FDA regulations given its circumstances, *id.* at 460, Warner-Lambert actually understood very well what the FDA regulations required of it but strategically ignored them. *See Purepac v. TorPharm*, 354 F.3d at 885. Indeed, Organon maintained that its '099 patent actually did cover an approved use. (Amundson Decl. Ex. 14 at 2 ("[U]nlike with the '479 gabapentin patent, there has been no admission by the ['099] patent holder [Organon] to FDA that the ['099] patent does not claim an approved use."). Here, Warner-Lambert has acknowledged that the treatment of neurodegenerative diseases differs from the treatment of epilepsy for FDA purposes. *See Purepac v. Thompson*, 238 F. Supp. 2d at 209 n.25. Third, Purepac will show that Warner-Lambert listed the '479 patent in the Orange Book while it knew that it could not reasonably assert a claim of infringement as required by 21 U.S.C. § 355(b). A claim of inducing

infringement of a method-of-use patent covering an off-label use could not reasonably be asserted since the ANDA labeling would not—and could not—refer to the off-label use. In addition, Purepac will show that Warner-Lambert kept the '479 patent listed even after it discovered that a claim of infringement would be unreasonable because its own research had revealed that gabapentin was ineffective in treating neurodegenerative diseases. (Defenses ¶ 22.)

These distinctions are particularly significant because, as the Court acknowledged in *Organon*, Orange Book submissions are not protected by *Noerr-Pennington*, and therefore not subject to the "objectively baseless" standard. *See* 293 F. Supp. 2d at 458-59. Warner-Lambert's subjective intent and understanding of its obligations under FDA regulations when it submitted the '479 patent for Orange Book listing are therefore relevant, particularly in light of its overall monopolization scheme.

D. Warner-Lambert Filed and Pursued Objectively Baseless Lawsuits

Purepac has alleged in detail how, as part of Warner-Lambert's overall monopolization scheme, Warner-Lambert filed and pursued objectively baseless lawsuits asserting infringement of the '476 and '479 patents. Warner-Lambert argues that earlier decisions by Judge Lifland and decisions by other courts in other cases establish as a matter of law that Warner-Lambert's '476 and '479 patent infringement lawsuits had an objective basis. Warner-Lambert is wrong.

As an initial matter, like its other arguments, Warner-Lambert's arguments regarding its '476 and '479 patent infringement suits ignore Purepac's overall monopolization claim. None of the opinions that Warner-Lambert relies on considered the legality or anticompetitive effect of its lawsuits in that context. (Pls.' Br. 39-46.)

But even when viewed in isolation, Purepac's allegations of sham litigation state a claim upon which relief can be granted. Where, as here, the parties dispute the predicate facts relating to probable cause, sham-litigation claims cannot be resolved upon a Rule 12(b)(6) motion to

dismiss. *See In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 360-61 (D. Mass. 2004). Here, as in *Relafen*, "[t]he state of [Warner-Lambert's] knowledge at the time of filing [and at various stages of the lawsuits] . . . [i]s [] a disputed factual issue that the Court [i]s duty-bound to submit to the jury." *Id.* at 362; (Countercl. ¶¶ 141-47).

1. A Full Record Will Show That Warner-Lambert's '476 Patent Infringement Claims Were Sham

Purepac has alleged that Warner-Lambert commenced the Capsule Action without any presuit investigation, knowing there was no objective basis for asserting the '476 patent. (Countercl. ¶¶ 141-47, 158-62.) Purepac has also alleged that Warner-Lambert delayed discovery as much as possible and, after discovery, continued litigating and filed another lawsuit despite having received conclusive evidence of noninfringement. (*Id.* at ¶¶ 164-68, 170-75.)

Judge Lifland concluded that these disputed factual allegations clearly state a sham-litigation claim. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *5-6. Other courts have concluded the same in similar conditions. In *Hoffman-LaRoche, Inc. v. Genpharm, Inc.*, for instance, the court denied a motion to dismiss sham-litigation claims, holding that the following fact questions relating to probable cause precluded dismissal:

> [I]nvolves the determination of whether plaintiffs undertook a reasonable investigation before filing suit, whether plaintiffs knew or should have known that [the patent defendant] had not infringed the . . . patents, and whether a reasonable litigant could have realistically expected success on the merits at the time the suit was filed.

50 F. Supp. 2d 367, 380 (D.N.J. 1999); *see also* III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law*, ¶ 706 at 196 (2002) ("[T]he monopolist should be compelled to request a reasonable opportunity to inspect the allegedly infringing process before attacking.").

Warner-Lambert argues that the denial of Purepac's § 285 motion in *Warner-Lambert Co. v. Purepac Pharmaceutical Co.*, Nos. 98-2749 & 99-5948, 2003 WL 21698310 (D.N.J. May

22, 2003), and the denial of Apotex's Rule 11 motion in *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 2003 WL 22887861 (N.D. Ill. Dec. 4, 2003), preclude as a matter of law that Warner-Lambert's '476 patent infringement claims against Purepac were objectively baseless. Warner-Lambert is wrong.

In *Warner-Lambert v. Purepac*, Judge Lifland denied Purepac's § 285 motion concerning the '476 patent infringement claims due to "insufficient evidence . . . that [Warner-Lambert]'s claim of infringement was unreasonable." 2003 WL 21698310, at *4. It would be improper to foreclose Purepac from taking discovery as to its sham-litigation allegations in this action merely by cross-referencing Judge Lifland's § 285 decision in *Warner-Lambert v. Purepac*. First, Judge Lifland specifically denied Warner-Lambert's motion to dismiss Purepac's sham-litigation allegations and then bifurcated and stayed Purepac's antitrust claims. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *5-6, *12-13. Because that stay has remained in place, Purepac has not taken discovery on those antitrust claims.[10] Second, Judge Lifland's § 285 decision only concerned Warner-Lambert's '476 patent infringement claims, and it did not address whether Warner-Lambert's pursuit of the Capsule and Tablet Actions as a whole—including its '479 patent infringement claims—were sham. *See Sumitomo Mitsubishi Silicon Corp. v. MEMC Elec. Materials, Inc.*, No. 05-2133, 2007 WL 2318903, at *12 (N.D. Cal. Aug. 13, 2007) (holding that, while it may be probative, a denial of a motion for attorney fees should not foreclose a sham-litigation claim as a matter of law where the fee motion did not address all issues raised in the sham-litigation claim), *aff'd in part and vacated in part on other grounds*, 248 Fed. Appx. 199 (Fed. Cir. 2007). Third, Judge Lifland ruled on Purepac's § 285 motion without a trial or hearing because Warner-Lambert withdrew its '476 patent infringement claims in February 2001 and did

[10] In contrast, in *Q-Pharma, Inc. v. Andrew Jergens Corp.*, 360 F.3d 1295 (Fed. Cir. 2004), cited by Warner-Lambert, the antitrust claimant had already taken discovery on its sham-litigation claim. *Id.* at 1298-99.

not even oppose Purepac's summary-judgment motion on those claims. (Countercl. ¶ 176.) Moreover, in ruling on Purepac's § 285 motion, Judge Lifland improperly decided disputed issues of material fact. Purepac has not yet had an opportunity to appeal Judge Lifland's § 285 decision since final judgment has not been entered in *Warner-Lambert v. Purepac*.

The same applies with greater force to Magistrate Judge Keys' and Judge Plunkett's Rule 11 opinions in *Warner-Lambert Co. v. Apotex Corp*. *See* No. 98 C 4293, 2003 WL 21754948 (N.D. Ill. July 28, 2003); No. 98 C 4293, 2003 WL 22887861 (N.D. Ill. Dec. 4, 2003). What's more, in determining probable cause the Court must rely on the facts alleged in Purepac's counterclaims and may not "make factual findings in this case based on the facts recited in the opinions of other courts," in cases where Purepac was not a party or that related to other issues. *In re Wellbutrin SR Antitrust Litig.*, Nos. 04-5525, 04-5898 & 05-396, 2006 WL 616292, at *6 (E.D. Pa. Mar. 9, 2006). That is especially true here because Purepac had no ability to influence the record or arguments in *Warner-Lambert v. Apotex*, and because Warner-Lambert's actions against Purepac differed from its actions against Apotex. For instance, while Warner-Lambert only filed one lawsuit against Apotex, it filed two consecutive lawsuits against Purepac. This was one of the reasons Judge Lifland denied Warner-Lambert's motion to dismiss in 2000. *Warner-Lambert v. Purepac*, 2000 WL 34213890, at *5.

2. A Full Record Will Show That Warner-Lambert's '479 Patent Infringement Claims Were Sham

To prevail on infringement for the '479 patent, Warner-Lambert had to demonstrate that, after ANDA approval, Purepac would induce doctors to infringe the claimed method. A full record will reveal that, given Warner-Lambert's knowledge when it filed the Capsule and Tablet Actions, it did not have an objective basis for believing that Purepac would induce infringement

(Countercl. ¶¶ 141-47; Defenses ¶ 22), much less had a "specific intent" to do so.[11]

Warner-Lambert knew, for instance, that the method recited in the '479 patent—using gabapentin to treat neurodegenerative diseases—was commercially insignificant and clinically ineffective, and that any sales attributable to such treatment resulted from Warner-Lambert's fraudulent marketing activities. (Defenses ¶¶ 20, 22-23.) As the Federal Circuit observed:

> [O]nly about 2.1% of the prescriptions written for gabapentin from August 1999 to July 2000 were for neurodegenerative diseases. . . . [I]t defies common sense to expect that [Purepac] will actively promote the sale of its approved gabapentin, in contravention of FDA regulations, for a use that (a) might infringe Warner-Lambert's patent and (b) constitutes such a small fraction of total sales.

Warner-Lambert, 316 F.3d at 1365. Purepac will demonstrate that Warner-Lambert's inducement arguments were not just legally irrelevant, *see id.* at 1364 ("[I]f a physician, without inducement by [Purepac], prescribes a use of gabapentin in an infringing manner, [Purepac's] knowledge [of that allegedly infringing off-label use] is legally irrelevant."), but also disingenuous given Warner-Lambert's knowledge about the clinical ineffectiveness of gabapentin anhydrous for treating neurodegenerative diseases.

Judge Lifland therefore concluded that these allegations state a claim for sham litigation. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *5-6.

Warner-Lambert relies heavily on Judge Schall's concurring opinion in *Allergan* for the proposition that it had a reasonable basis in law for its interpretation of 35 U.S.C. § 271(e)(2).

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[11] Since 1990 "precedent holds that mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363-64 (Fed. Cir. 2003) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553-54 (Fed. Cir. 1990), and *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990)). But no matter what degree of intent Warner-Lambert had to show to prove inducement, Warner-Lambert's knowledge about the clinical ineffectiveness of gabapentin anhydrous for treating neurodegenerative diseases precluded any reasonable belief that Purepac would induce infringement of the '479 patent.

(Pls.' Br. 44-45.) Although Purepac disagrees with Judge Schall's opinion on that issue, it is beside the point. Even Judge Schall recognized that Allergan submitted proof that the alleged infringer advertised and publicized off-label uses, but "Warner-Lambert was not able to present evidence tending to show that Apotex had encouraged, or would encourage, doctors to infringe Warner-Lambert's neurodegenerative method patent." *Allergan*, 324 F.3d at 1336.

Warner-Lambert also argues that Judge Lifland's and Judge Plunkett's early-stage summary-judgment opinions in *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 98-2749, 1999 U.S. Dist. LEXIS 23378 (D.N.J. Aug. 25, 1999), and *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 1999 WL 259946 (N.D. Ill. Apr. 8, 1999), respectively, show that it had an objective basis for its suits. Warner-Lambert made the exact same argument when it moved to dismiss Purepac's counterclaims in 2000. (Amundson Dec. Ex. 15 at 1-2, 17-20.) But Judge Lifland flatly rejected that argument, holding, among other things, that "[t]he mere fact that summary judgment was denied in the 98-2749 litigation does not, in and of itself, preclude Purepac's counterclaims of antitrust violations." *Warner-Lambert v. Purepac*, 2000 WL 34213890, at *6.

In Purepac's brief opposing Warner-Lambert's 2000 motion to dismiss, Purepac explained that "[w]ith a full record, Purepac will show . . . that Warner-Lambert knew that the methods covered by its '479 patent were commercially insignificant and clinically ineffective . . . that Warner-Lambert itself illegally promoted off-label usage . . . and therefore likely has created any infringement it now challenges." (Amundson Decl. Ex. 16 at 25.) Judge Lifland therefore denied Warner-Lambert's motion to dismiss Purepac's sham-litigation allegations regarding the '479 patent. *See Warner-Lambert v. Purepac*, 2000 WL 34213890, at *6.

That still holds. Survival of summary judgment, especially at an early stage in the lawsuit, should not be assumed to establish probable cause as a matter of law because "evidence suggesting a genuine issue of material fact does not undergo 'extensive testing' on summary

judgment, and significantly, undergoes no testing with respect to the credibility of the witnesses."[12] *Relafen*, 346 F. Supp. 2d at 363-64 (permitting trial of sham-litigation counterclaim even though the underlying patent-infringement claims survived summary judgment).[13]

Finally, as discussed above, the Court should not base its decision on the factual determinations of other courts in other cases, like *Warner-Lambert v. Apotex*. *See Wellbutrin*, 2006 WL 616292, at *6.

VI. Purepac Properly Alleges Antitrust Injury and Standing

A. But for Warner-Lambert's Monopolization Scheme Purepac Would Have Entered the Market Earlier

Warner-Lambert asserts that Purepac has failed to allege antitrust injury because no proximate cause exists between "the three alleged market-blocking activities by Warner-Lambert" and the delay in Purepac's launch in October 2004. (Pls.' Br. 25-28.) Warner-Lambert additionally argues that no proximate cause exists between the first 30-month stay resulting from the '476 patent listing and litigation and Purepac's market foreclosure because (a) the first stay ended before Purepac received its approvable letter from the FDA, and (b) during the first stay, the unchallenged '544 patent and the second 30-month stay resulting from the '482 patent listing and litigation prevented Purepac from entering the market. (Pls.' Br. 25-28.)

Warner-Lambert's arguments fail as a matter of fact and law. Indeed, "the existence of an

[12] Indeed, in *Warner-Lambert Co. v. Apotex Corp.*, Apotex challenged the propriety and truthfulness of the affidavits Warner-Lambert submitted in opposition to Apotex's summary-judgment motion, and the court struck them on certain issues. No. 98 C 4293, 1999 WL 259946, at *4-6 (N.D. Ill. Apr. 8, 1999).

[13] *See also Film Tec Corp. v. Hydranautics*, 67 F.3d 931, 938 (Fed. Cir. 1995) ("a preliminary success on the merits does not preclude a court from concluding that litigation was baseless"); *Calloway v. Marvel Entm't Group*, 854 F.2d 1452, 1473 (2d Cir. 1988), *rev'd on other grounds*, 493 U.S. 120 (1989) ("[I]t is . . . entirely possible that a baseless factual claim will survive a motion for summary judgment.").

antitrust injury is not typically resolved through a motion to dismiss." *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995); *see also In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003) ("When a defendant relies upon the existence of an independent cause [ ] such cause must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury.").

First, Warner-Lambert's assertion that Purepac launched its product "17 months after the last blocks had been lifted" is factually incorrect. (Pls.' Br. 27.) The exclusionary effects of Warner-Lambert's monopolization scheme lasted until September 2004, shortly before Purepac launched gabapentin products in October 2004. Until then, FDA approval of Purepac's ANDAs was contested (and temporarily stayed) in litigation with the FDA and Apotex, which directly resulted from Warner-Lambert's fraudulent Orange Book submissions, its refusal to delist the '479 patent, and its sham lawsuits. *See, e.g.*, *Purepac v. Thompson*, 238 F. Supp. 2d at 197 ("Determining the use claimed by the '479 patent is at the heart of this case."). An earlier launch meant Purepac had to accept the possibility of a court-ordered revocation of marketing ability and risk losing a portion of its 180-day generic exclusivity. This regulatory barrier to entry would not have existed but for Warner-Lambert's monopolization scheme. (Countercl. ¶¶ 148-57.)[14] Thus, Warner-Lambert's acts were the proximate cause of Purepac's market foreclosure.

Other courts have found antitrust injury and causation in similar circumstances. For instance, in *Dr. Reddy's Laboratories, Ltd. v. AAIPharma, Inc.*, the court held that FDA inquiries delaying an ANDA applicant's market entry did not break the chain of causation between the defendant's alleged improper conduct and the ANDA applicant's injury, where the improper conduct was alleged to have caused the FDA to make the inquiries, "notwithstanding the fact that [the defendant] d[id] not have control over the FDA." No. 01 Civ. 10102, 2002 WL 31059289,

[14] Also see the cases cited *supra* in footnote 2.

at *10-11 (S.D.N.Y. Sept. 13, 2002). Similarly, in *Eli Lilly & Co. v. American Cyanamid Co.*, the court held that the FDA's delay in approving a generic drug manufacturer's bulk cefaclor suppliers did not break the chain of causation where the anticompetitive conduct had allegedly foreclosed the generic drug manufacturer from access to alternative FDA-approved suppliers. No. IP95-536-C, 2001 WL 30191, at *5 (S.D. Ind. Jan. 1, 2001).

Second, Warner-Lambert's proximate-cause arguments improperly compartmentalize Purepac's monopolization allegations. Purepac need not allege proximate cause or antitrust injury separately for each component of Warner-Lambert's monopolization scheme:

> [T]his court will not evaluate whether each and every anticompetitive act upon which Biovail's antitrust claims are based directly caused Biovail injury. Instead, it will determine whether Biovail was injured by the anticompetitive conduct as a whole . . . .

Biovail, 49 F. Supp. 2d at 767; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (same).

Nor does Purepac need to allege or prove that Warner-Lambert's anticompetitive acts were the sole cause of its injury. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury."). And whether Warner-Lambert's monopolization scheme materially contributed to the injury raises a fact question not suitable for resolution before discovery. *See Cont'l Ore*, 370 U.S. at 702 (holding that the jury should determine whether the anticompetitive conduct "materially contributed" to the injury).

Accordingly, Warner-Lambert's argument that the '544 patent and the second 30-month stay resulting from the '482 patent precluded causation between the '476 patent listing and litigation and Purepac's market foreclosure is not only irrelevant, but also wrong. Warner-Lambert's argument assumes that the second 30-month stay due to the '482 patent was

legitimately obtained. But Purepac has alleged in detail how that stay was a direct result of Warner-Lambert's monopolization scheme, including the fraudulent listing of the '476 patent and Warner-Lambert's wrongful conduct before the Patent Office, which enabled Warner-Lambert to time the second 30-month stay. (Countercl. ¶¶ 90, 118-19, 122-23.) Warner-Lambert's argument that the FDA's April 2002 approvable letter precluded causation with regard to the '476 patent listing and litigation because the first 30-month stay expired before the FDA sent that letter is therefore equally irrelevant. The second 30-month stay resulting from Warner-Lambert's monopolization scheme expired eight months **after** the FDA sent the approvable letter. What's more, because the second 30-month stay guaranteed Warner-Lambert market exclusivity until December 2002, Purepac had "little practical incentive" to seek early FDA approval. *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000). Rather, Purepac was "better served to direct [its] resources toward" obtaining final judgment in the lawsuits as soon as possible to end the stays. *Id.*

That said, Warner-Lambert's argument that tentative FDA approval is required to allege antitrust injury squarely contradicts the law in the Third Circuit. (Pls.' Br. 32.) *See, e.g.*, *Bristol-Myers Squibb v. Ben Venue*, 90 F. Supp. 2d at 544-46 (holding that FDA approval is not required to allege antitrust injury); *Wellbutrin SR/Zyban*, 281 F. Supp. 2d at 756-57 (same); *see also Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943 (N.D. Ill. 2003) (holding that even an ANDA application is not necessary to allege antitrust injury), *rev'd on other grounds*, 372 F.3d 899 (7th Cir. 2004).

Warner-Lambert relies on a Southern District of Florida opinion that expressly points out that other courts have not required tentative FDA approval for antitrust injury, citing, among other cases, *Bristol-Myers Squibb v. Ben Venue* and *Xechem*. *See In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 n.30 (S.D. Fla. 2004). The *Terazosin Hydrochloride*

court distinguished *Bristol-Myers Squibb v. Ben Venue* because, as here, that case involved antitrust claims by generic manufacturers who paid to defend against sham litigation, while the *Terazosin Hydrochloride* plaintiffs were purchasers who did not have to defend against sham litigation. *Id.*

Warner-Lambert's reliance on *Bristol-Myers Squibb Co. v. Copley Pharmaceuticals, Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), is also inappropriate. That opinion was strongly criticized in *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd.*, 480 F. Supp. 2d 462, 468 (D. Mass. 2007), for relying on *Andrx Pharmaceuticals, Inc. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000). The *Copley* court had improperly relied on the *Andrx* opinion in concluding that FDA approval was required for antitrust injury. The *Amgen* court pointed out that the D.C. Circuit in *Andrx* had later "clarified that [to show antitrust injury] the anticipation of FDA approval may suffice since all that is necessary is demonstration of intent and preparedness to enter a market." *Amgen*, 480 F. Supp. 2d at 468 (citing *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 807 (D.C. Cir. 2001)); *see also Xechem*, 274 F. Supp. 2d at 943 n.2 (similarly criticizing *Copley*).[15]

Here, Purepac has alleged that it had "intent and preparedness" to enter the market before October 2004 but that Warner-Lambert's monopolization scheme directly and proximately delayed Purepac's market entry until then by (a) delaying the '482 patent's issuance, (b) imposing consecutive 30-month stays of ANDA approval, (c) burdening Purepac with sham lawsuits, and (d) causing Purepac to get entangled in regulatory disputes and litigation over FDA approval of its ANDAs. (Countercl. ¶¶ 103, 157, 181.) Those allegations sufficiently state antitrust injury, even though the 30-month stays expired before FDA approval. *See, e.g.*, *Wellbutrin SR/Zyban*, 281 F. Supp. 2d at 756-57 (holding that antitrust injury was alleged despite

[15] Moreover, unlike Copley, Purepac was the first filer, with no other generics standing in the way of market entry. *See Amgen*, 480 F. Supp. 2d at 468 (distinguishing *Copley* on that ground).

lack of FDA approval after the 30-month stays had expired because it was reasonable to assume that sham lawsuits had "directed resources away from FDA approval" and thus resulted in "a delay of FDA approval"); *Xechem*, 274 F. Supp. 2d at 943-44 (holding that antitrust injury was alleged despite the lack of ANDA filing). Warner-Lambert disputes that Purepac was about to receive FDA approval and had the "intention and preparedness" to launch before October 2004, but that is a question of fact not normally resolved in a Rule 12(b)(6) motion. *See Xechem*, 274 F. Supp. 2d at 942-44.

B. Warner-Lambert's Monopolization Scheme Significantly Raised Purepac's Cost of Market Entry by Causing Purepac to Incur Millions in Legal Fees

In arguing that Purepac failed to allege antitrust injury, Warner-Lambert erroneously focuses exclusively on the 30-month stays. Warner-Lambert's monopolization scheme has also caused Purepac other kinds of antitrust injury, including an increase in Purepac's cost of market entry due to many millions of dollars in legal fees. For generic drug companies, such additional market entry costs significantly impact the bottom line, and thus create additional barriers to entry. That constitutes antitrust injury. *See, e.g.*, *Bristol-Myers v. Ben Venue*, 90 F. Supp. 2d at 546; *Novo Nordisk of N. Am. v. Genentech*, 885 F. Supp. 522, 525 (S.D.N.Y. 1995).

VII. Purepac States an Unfair-Competition Claim Under New Jersey Law

The factual allegations supporting Purepac's antitrust counterclaims also support its New Jersey common-law unfair-competition counterclaim. *See, e.g.*, *Syncsort, Inc. v. Innovative Routines Int'l, Inc.*, No. 04-3623, 2005 WL 1076043, at *10, *13-14 (D.N.J. May 6, 2005) (denying motion to dismiss Section 2 Sherman Act claim and New Jersey common-law unfair-competition claim on the same bases, including sham-litigation allegations); *Warner Lambert v. Purepac*, 2000 WL 34213890, at *10 ("[New Jersey] unfair competition claims also apply to one who interferes by instituting or threatening to institute groundless litigation against a

competitor"). Accordingly, for the reasons discussed above, Warner-Lambert's motion to dismiss Purepac's New Jersey common-law unfair-competition claim also fails.

CONCLUSION

In summary, Purepac's answer and counterclaim satisfies Rule 12(b)(6)'s standard for pleading unclean hands, patent misuse, antitrust violations, and a state-law cause of action. Consequently, the Court should deny Warner-Lambert's motion in all respects.

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